3584679-2-00-01

ıdo Pharmaceuticals Inc.

FDA Facsimile Approval 07/25/1999

Safety report # Percocet2000-00345

MF/Other report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: 43.000 or Date of Birth:	3. Sex	4. Weight
Case 309 in confidence		☑ female ☐ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☑ death 1999
- ☐ life threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/da/yr): 1999

4. Date of this report (mo/da/yr): 09/26/2000

5. Describe event or problem

Citation: Litovitz, Toby. 1999 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. American Journal of Emergency Medicine (pre-publication) 2000.

Initial notification (9/21/00):
A 43-year-old female was transported to the hospital with mental status changes. She was found to be HYPOTENSIVE with HEPATIC and RENAL FAILURE. History obtained from the family revealed that the patient was taking Percocet but the dose and duration of therapy was not known. On admission, laboratory tests showed an acetaminophen level of 20 mcg/mL, AST 1000s U/L, ALT 1000s U/L, SCr 2.0 mg/dL, CO2 6 mEq/L, K 6.1 mEq/L, PT 55.3 sec, PTT 38 sec, and ammonia 147 ug/dL. She received (cont. on following page)

6. Relevant tests/laboratory data, including dates

Test	Value	Units	Date
acetaminophen drug level	20	mcg/mL	

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol abuse, hepatic/renal dysfunction, etc.)

Drug abuse; unknown medical history.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Percocet Endo
- #2

2. Dose, frequency & route used
- #1 UNK PO
- #2

3. Therapy dates (if unknown, give duration)
- #1 Unknown
- #2

4. Diagnosis for use (indication)
- #1 UNK
- #2

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office -name/address (& mfring site for devices)

Endo Pharmaceuticals Inc.
223 Wilmington West Chester Pike
Chadds Ford, PA 19317

2. Phone Number: (610) 558-9800

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☑ literature
- ☐ consumer
- ☑ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/da/yr): 09/21/2000

5. (A) NDA # 85-106
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☑ 15-day
- ☐ 10-day ☐ periodic
- ☑ initial ☐ follow-up #

8. Adverse event term(s)
Drug abuse
Hypotension NOS

9. Mfr. report number: Percocet2000-00345

E. Initial reporter

1. Name & address
Dr. Toby Litovitz
American Assoc of Poison Control Centers
Washington DC, 20016 USA

phone #: (202) 362-7493

2. Health professional? ☑ yes ☐ no

3. Occupation: Physician

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☑ unk

DSS

FDA 3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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Section B5, Description of event/problem continuation (as necessary):

a loading dose of N-acetylcysteine orally, and was started on dopamine and norepinephrine infusions for hypotension. She was not considered a good candidate for liver transplant because of a history of drug abuse. She expired on the 2nd hospital day.

This adverse event report was received from R.W. Johnson Pharmaceutical Research Institute who filed the case as a "15-day report" under Mfr report # PRIUSA2000006672 with Tylox (oxycodone and acetaminophen) as the suspect drug. Upon receipt of follow-up information, it was found that the patient had actually taken Percocet.

Section B6, Relevant tests/laboratory data continuation (as necessary):

Test	Value	Units	Date
AST	1000	U/L	
ALT	1000	U/L	
SCr	2.0	mg/dL	
CO2	6	mEq/L	
K	6.1	mEq/L	
PT	55.3	sec	
PTT	38	sec	
Ammonia	147	ug/dL	

Section B7, Other relevant history continuation (as necessary):

Sections C1-8, Suspect medication(s) continuation (as necessary):

Name	Dose, frequency & route used	Therapy dates	Diagnosis for use	Lot #/ Exp. date	Event abated/ Event reappeare

Section C10, Concomitant medical products continuation (as necessary):

Name	Therapy dates

Section G8, Adverse event term(s) continuation (as necessary):

Hepatic failure
Renal failure acute